

REMARKS/ARGUMENTS

Claims 57, 58, 61-64, 66-69, 72, 78-81, 83-85, 87, and 89-126 are pending.

Applicants note with appreciation the allowance of claims 69, 72, 78-80, 91-95, 99-101, 111-113, and 117-123.

Claims 57, 58, 61-64, 66-68, 81, 83-85, 87, 89, 90, 96-98, 102-110, 114-116, and 124-126 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Durand et al. (US 3,893,451) in view of Brockway et al. (US 4,846,191), Iwata et al. (US 6,019,728), and Pohndorf et al. (US 5,353,800).

Applicants would like to thank the Examiner for the courteous telephone interview extended to Applicants counsel, Chun-Pok Leung, on September 14, 2005. During the telephone interview, the Examiner and counsel discussed the rejection of the independent claims under 35 U.S.C. § 103(a) and the rejection of the dependent claims which recite that the pressure transmission catheter has a length of about 2 mm. The Examiner indicates that he is willing to reconsider the rejection of the dependent claims that recite the 2 mm length, and may reconsider the rejection of the independent claims if appropriate arguments are made.

Section 103 Rejection

Each of independent claims 57, 64, 81, and 96 recites an implantable pressure transmitting catheter having a lumen filled entirely with a pressure transmitting viscous gel and being sufficiently short in length so that the pressure transmitting viscous gel provides a sufficient dynamic response. This feature is discussed, for instance, at page 11, lines 8-13. When the length of the pressure transmitting catheter is sufficiently short, the lumen can be filled entirely with a viscous gel without using a low-viscosity fluid but still provides a sufficient dynamic response.

Applicants respectfully submit that independent claims 57, 64, 81, and 96 are patentable over Durand et al., Brockway et al., Iwata et al., and Pohndorf et al. because, for instance, they do not teach or suggest the recited features.

Durand et al. discloses a liquid pressure transmission medium and is devoid of any teaching of a viscous gel. As the Examiner further recognizes, Durand et al. does not teach an implantable monitor housing the transducer and the signal processing equipment. The Examiner cites Brockway et al. for disclosing those missing features.

Brockway et al. discloses the use of a combination of a low viscosity liquid and a gel of much higher viscosity. Nothing in Durand et al. and Brockway et al., however, disclose or suggest the use of a viscous gel without the use of a low-viscosity fluid. In Brockway et al., "Gel 30 provides a means of retaining fluid and is of a viscosity much higher than that of fluid 29" (col. 5, lines 40-42). Thus, the gel 30 is used for retaining the low viscosity fluid 29, which is primarily responsible for pressure transmission.

Iwata et al. is cited for disclosing the use of a silicone gel 9 as a biocompatible pressure transmitting medium for transmitting pressures in an inner space 27 of a blood vessel catheter 1. Applicants respectfully submit that the disclosure of Iwata et al. does not provide the motivation to modify Durand et al. and/or Brockway et al. to fill the lumen of the catheter entirely with a viscous gel. In Brockway et al., the purpose of the gel 30 is not for pressure transmission, but to maintain integrity of the device. As discussed at column 5, lines 51-65, the gel 30 blocks the opening at the distal tip 22 of the open cavity 31, and serves to keep the pressure transmission low viscosity fluid 29 inside the catheter 20:

Since the molecular entities of gel 30 are cross-linked, and since gel 30 has a tendency to adhere to the walls of cavity 31, gel 30 will not migrate out of cavity 31 or be washed away by body fluids or tissue impinging on distal tip 22, as would occur in a simple fluid-filled catheter. The ability of gel 30 to maintain its integrity is particularly key to monitoring blood pressure, where wash-out of material at the distal tip 22 of catheter 20 would result in the formation of fibrinous tissue within the lumen 28, leading to loss of fidelity of the pressure measurement. In addition, gel 30 is of a viscosity such that it can be displaced by small

amounts within cavity 31 of catheter 20 without building up significant stresses which could result in a pressure differential across gel 30.

Moreover, Iwata et al. does not cure other deficiencies of Durand et al. and Brockway et al., in that it also fails to teach a pressure transmitting catheter that is sufficiently short in length so that the pressure transmitting viscous gel provides a sufficient dynamic response.

Pohndorf et al. is cited for disclosing a needle having a length of about one inch (col. 4, lines 55-56). Applicants note, however, that Pohndorf et al. is devoid of any discussion of using a viscous gel as a pressure transmitting gel and the need to make the catheter sufficiently short to provide a sufficient dynamic response. Pohndorf et al. merely states that experiments showed that a flat frequency response in the range between zero and approximately twenty hertz is achieved with a twenty-two gauge needle having a length of about one inch (col. 4, lines 50-56).

In short, Applicants respectfully assert that the references fail to teach or suggest the need to limit the length of a pressure transmitting catheter to be sufficiently short when the lumen of the catheter is filled entirely with a pressure transmitting viscous gel, so that the pressure transmitting viscous gel provides a sufficient dynamic response.

Furthermore, the rejection appears to benefit from the exercise of hindsight. Federal Circuit "case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references." *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999) (citations omitted).

In this case, the inventors sought to provide a pressure transmitting catheter having a lumen filled entirely with a pressure transmitting viscous gel which would still provide a sufficient dynamic response. The inventors discovered that it was necessary to limit the length of a pressure transmitting catheter to be sufficiently short so that the pressure transmitting viscous gel provides a sufficient dynamic response (see page 11, lines 10-13).

Durand et al. and Brockway et al. do not disclose or suggest the use of a viscous gel as the pressure transmitting fluid. In Brockway et al., the purpose of the gel 30 is not for pressure transmission, but to maintain integrity of the device by keeping the pressure transmission low viscosity fluid 29 inside the catheter 20. Although Iwata et al. discloses the use of a silicone gel for pressure transmission, it is devoid of any discussion of the length of the catheter and dynamic response. The disclosure of a twenty-two gauge needle having a length of about one inch in Pohndorf et al. does not cure the deficiencies of Durand et al., Brockway et al., and Iwata et al.

To guard against the tempting trap of hindsight, the evidence of a suggestion, teaching, or motivation to combine "must be clear and particular." *Dembiczak*, 50 U.S.P.Q.2d at 1617 (citation omitted). "Broad conclusory statements regarding the teaching of multiple references, standing alone, are not 'evidence.'" *Id.* (citations omitted). In this case, Applicants believe "clear and particular" evidence of a suggestion, teaching, or motivation to combine is lacking. Significantly, none of the references establish the connection between the length of the catheter and a sufficient dynamic response when a viscous gel is used as the pressure transmitting fluid.

Without "clear and particular" evidence of a suggestion, teaching, or motivation to combine, the rejection may be construed as being the result of simply piecing together distinct teachings of multiple references based on the present disclosure. "Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight." *Id.* (citing *Interconnect Planning Corp. v. Feil*, 227 U.S.P.Q. 543, 551 (Fed. Cir. 1985)). Just because different aspects of similar types of devices may be used together does not constitute evidence of a motivation to combine them.

For at least the foregoing reasons, Applicants respectfully submit that claims 57, 58, 61-64, 66-68, 81, 83-85, 87, 89, 90, 96-98, 102-110, 114-116, and 124-126 are patentable over Durand et al., Brockway et al., Iwata et al., and Pohndorf et al.

Claims Reciting a Length of About 2 mm

Dependent claims 58, 124, 125, and 126 further recite that the pressure transmission catheter has a length of about 2 mm.

Pohndorf et al. is cited for disclosing a twenty-two gauge needle having a length of about one inch (col. 4, lines 50-56). Because one inch is 25.4 mm, which is over 10 times the recited length of about 2 mm, Applicants respectfully submit that these claims are patentable as being directed to additional features of the present invention, as well as by being dependent from allowable independent claims for the reasons discussed above.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,



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